

AMENDMENTS TO THE CLAIMS

1. **(Canceled)**
2. **(Currently amended)** A method of preventing onset of Type I diabetes in a mammal predisposed to Type I diabetes, comprising implanting a dose of insulin-producing cells encapsulated in a biologically-compatible membrane into an implantation site in said mammal prior to onset of Type I diabetes, wherein said dose is at least one order of magnitude less than that necessary to achieve normoglycemia in a mammal of the same species with type I diabetes.
3. **(Previously presented)** The method of Claim 2, wherein said cells are from a primary cell source.
4. **(Previously presented)** The method of Claim 3, wherein said cells are pancreatic islet cells.
5. **(Previously presented)** The method of Claim 2, wherein said cells are encapsulated in a conformal coating.
6. **(Previously presented)** The method of Claim 5, wherein said conformal coating comprises polyethylene glycol (PEG).
7. **(Previously presented)** The method of Claim 2, wherein the insulin-producing cells are from the same species as the mammal.
8. **(Previously presented)** The method of Claim 2, wherein Type I diabetes is prevented without continuous immunosuppression.
9. **(Previously presented)** The method of Claim 2, wherein the cells are implanted intraperitoneally.

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

Experimental data showing that implanting a tolerizing (sub-therapeutic) dose of encapsulated insulin-producing cells into NOD mice prior to the animals developing diabetes protected these animals from diabetes for the rest of their natural lives as shown by their normoglycemia and lack of insulinitis.

Identification of Claims Discussed

2-9

Identification of Prior Art Discussed

USP 6,703,017 and 6,425,764

Proposed Amendments

The Applicant proposed to specify the dose of the insulin-producing cells implanted to prevent diabetes Type I.

Principal Arguments and Other Matters

The Applicant argued that claims 2-9 are novel over USP 6,703,017 and 6,425,764.

Results of Interview

The Examiner insisted that the data presented by the inventor showing prevention of Type I diabetes in non-obese diabetic (NOD) mice was not sufficient to show a method of preventing type I diabetes in human. According to the Examiner, only clinical data from human trials could be used for this purpose.